

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/036933

International filing date: 05 November 2004 (05.11.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/518,122
Filing date: 07 November 2003 (07.11.2003)

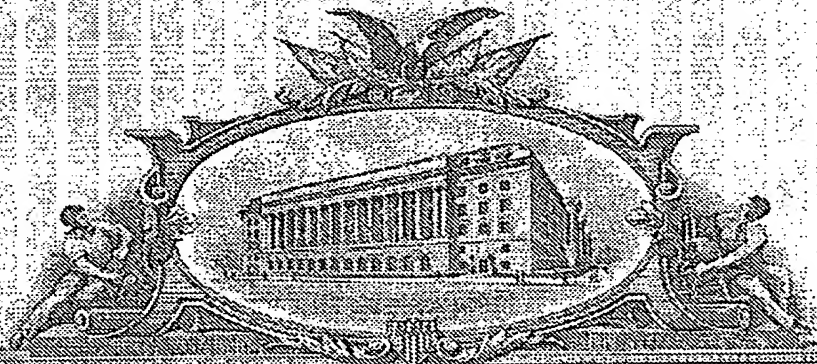
Date of receipt at the International Bureau: 10 January 2005 (10.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1268354



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 03, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/518,122

FILING DATE: November 07, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/36933



Certified By

Jon W Dudas

**Under Secretary
of Commerce for Intellectual Property
and Acting Director of the
United States Patent and Trademark Office**

17681 U.S. PTO
110703

PTO/SB/16 (08-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

ER457782637US

17681 U.S. PTO
60/518122

110703

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
James		BRUGGER		Newburyport, MA	
Additional inventors are being named on the (1) separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number: 21890					
OR					
<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country		Telephone		Fax	
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages 33					
<input type="checkbox"/> CD(s), Number					
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 15					
<input checked="" type="checkbox"/> Other (specify) Return Postcard					
<input type="checkbox"/> Application Date Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees.					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 16-2500					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
FILING FEE Amount (\$)					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:					

Respectfully submitted,

[Page 1 of 2]

Date 11/07/03

SIGNATURE

REGISTRATION NO. 38,720

TYPED or PRINTED NAME Mark Catan

(if appropriate)

Docket Number: 53951.104

TELEPHONE (212) 969-3000

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (08-03)

Approved for use through 07/31/2008. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket Number

53951.104

INVENTOR(S)/APPLICANT(S)

Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Chris S.	McDowell	Maynard, MA

[Page 2 of 2]

Number 2 of 2

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

PATENT
Attorney Docket: 53951-104

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
Applicant: James BRUGGER)	Group Art Unit: N/A
Serial No.: N/A)	Examiner: N/A
Filed: N/A)	
For: Improved Methods and Apparatus for)	
Leak Detection in Blood Processing)	
Systems)	

TRANSMITTAL TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Provisional Patent Application
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

This is a transmittal for filing a Provisional Application.

I. DOCUMENTS ENCLOSED:

- Provisional Application for Patent Cover Sheet
- Provisional Application
- Return Postcard

6383/53951-083 DCLIB1/218824 v1

12/27/2002 5:50:44 PM (18584)

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

Express Mail mailing number: ER 457782637US

Name of Person Mailing Paper: Melicia J. Lockett

11/7/03
Date of Deposit


Signature of Person Mailing Paper

II. PAYMENT OF FEES

- ☐ A check in the amount of _____ is enclosed to cover the above fee(s).
- ☐ Charge Proskauer Rose LLP's Deposit Account No. 16-2500 in the amount of \$_____.
- ☒ The Commissioner is authorized to charge Proskauer Rose LLP's Deposit Account No. 16-2500 for any fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part.

Respectfully submitted,

PROSKAUER ROSE, LLP

Dated: _____

11/7/2003

By: _____

Mark A. Catan
Reg. No. 38,720
Proskauer Rose, LLP
1585 Broadway
New York, NY 10036-8299

IMPROVED METHODS AND APPARATUS FOR LEAK DETECTION IN BLOOD
PROCESSING SYSTEMS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to the following US Patent Applications, each of which is hereby incorporated by reference as fully set forth in its entirety herein.

[0002] Pending US Patent Application Serial Number 10/037,429, filed 1/4/2002;

[0003] Pending US Patent Application Serial Number 09/907,872 filed 7/17/2001; and

[0004] Pending US Patent Application Serial Number 10/393,209 filed 3/20/2003.

FIELD OF THE INVENTION

[0005] The present invention relates to the detection of leaks (including needle-disconnects and other causes of loss of integrity) in extracorporeal blood circuits and more particularly to the application of air infiltration detection techniques to the detection of leaks in positive pressure return lines.

BACKGROUND

[0006] Many medical procedures involve the extraction and replacement of flowing blood from, and back into, a donor or patient. The reasons for doing this vary, but generally, they involve subjecting the blood to some process that cannot be carried out inside the body. When the blood is outside the patient it is conducted through machinery that processes the blood. The various processes include, but are not limited to, hemodialysis, hemofiltration, hemodiafiltration, blood and blood component collection, plasmapheresis, apheresis, and blood oxygenation.

[0007] One technique for extracorporeal blood processing employs a single "access," for example a single needle in the vein of the patient or a fistula. A volume of blood is cyclically drawn through the access at one time, processed, and then returned through the same access at another time. Single access systems are uncommon because they limit the rate of processing to half the capacity permitted by the access. As a result, two-access systems, in which blood is drawn from a first access, called an arterial access, and returned through a second access, called a venous access, are much faster and more common.

These accesses include catheters, catheters with subcutaneous ports, fistulas, and grafts.

[0008] The processes listed above, and others, often involve the movement of large amounts of blood at a very high rate. For example, 500 ml. of blood may be drawn out and replaced every minute, which is about 5% of the patient's entire supply. If a leak occurs in such a system, the patient could be drained of enough blood in a few minutes to cause loss of consciousness with death following soon thereafter. As a result, such extracorporeal blood circuits are normally used in very safe environments, such as hospitals and treatment centers, and attended by highly trained technicians and doctors nearby. Even with close supervision, a number of deaths occur in the United States every year due to undue blood loss from leaks.

[0009] Leaks present a very real risk. Leaks can occur for various reasons, among them: extraction of a needle, disconnection of a luer, poor manufacture of components, cuts in tubing, and leaks in a catheter. However, in terms of current technology, the most reliable solution to this risk, that of direct and constant trained supervision in a safe environment, has an enormous negative impact on the lifestyles of patients who require frequent treatment and

on labor requirements of the institutions performing such therapies. Thus, there is a perennial need in the art for ultra-safe systems that can be used in a non-clinical setting and/or without the need for highly trained and expensive staff. Currently, there is great interest in ways of providing systems for patients to use at home. One of the risks for such systems is the danger of leaks. As a result, a number of companies have dedicated resources to the solution of the problem of leak detection.

[0010] In single-access systems, loss of blood through the patient access and blood circuit can be indirectly detected by detecting the infiltration of air during the draw cycle. Air is typically detected using an ultrasonic air detector on the tubing line, which detects air bubbles in the blood. The detection of air bubbles triggers the system to halt the pump and clamp the line to prevent air bubbles from being injected into the patient. Examples of such systems are described in U.S. Pat. Nos. 3,985,134, 4,614,590, and 5,120,303.

[0011] While detection of air infiltration is a reliable technique for detecting leaks in single access systems, the more attractive two-access systems, in which blood is drawn continuously from one access and returned

continuously through another, present problems. While a disconnection or leak in the draw line can be sensed by detecting air infiltration, just as with the single needle system, a leak in the return line cannot be so detected. This problem has been addressed in a number of different ways, some of which are generally accepted in the industry.

[0012] The first level of protection against return line blood loss is the use of locking luers on all connections, as described in International Standard ISO 594-2 which help to minimize the possibility of spontaneous disconnection during treatment. Care in the connection and taping of lines to the patient's bodies is also a known strategy for minimizing this risk.

[0013] A higher level of protection is the provision of venous pressure monitoring, which detects a precipitous decrease in the venous line pressure. This technique is outlined in International Standard IEC 60601-2-16. This approach, although providing some additional protection, is not very robust, because most of the pressure loss in the venous line is in the needle used to access the patient. There is very little pressure change in the venous return line that can be detected in the event of a disconnection, so long as the needle remains attached to the return line.

Thus, the pressure signal is very weak. The signal is no stronger for small leaks in the return line, where the pressure changes are too small to be detected with any reliability. One way to compensate for the low pressure signal is to make the system more sensitive, as described in U.S. Pat. No. 6,221,040, but this strategy can cause many false positives. It is inevitable that the sensitivity of the system will have to be traded against the burden of monitoring false alarms. Inevitably this leads to compromises in safety. In addition, pressure sensing methods cannot be used at all for detecting small leaks.

[0014] Yet another approach, described for example in PCT application US98/19266, is to place fluid detectors near the patient's access and/or on the floor under the patient. The system responds only after blood has leaked and collected in the vicinity of a fluid detector. A misplaced detector can defeat such a system and the path of a leak cannot be reliably predicted. For instance, a rivulet of blood may adhere to the patient's body and transfer blood to points remote from the detector. Even efforts to avoid this situation can be defeated by movement of the patient, deliberate or inadvertent (e.g., the unconscious movement of a sleeping patient).

[0015] Still another device for detecting leaks is described in U.S. Pat. No. 6,044,691. According to the description, the circuit is checked for leaks prior to the treatment operation. For example, a heated fluid may be run through the circuit and its leakage detected by means of a thermistor. The weakness of this approach is immediately apparent: there is no assurance that the system's integrity will persist, throughout the treatment cycle, as confirmed by the pre-treatment test. Thus, this method also fails to address the entire risk.

[0016] Yet another device for checking for leaks in return lines is described in U.S. Pat. No. 6,090,048. In the disclosed system, a pressure signal is sensed at the access and used to infer its integrity. The pressure wave may be the patient's pulse or it may be artificially generated by the pump. This approach cannot detect small leaks and is not very sensitive unless powerful pressure waves are used, in which case the effect can produce considerable discomfort in the patient.

[0017] Clearly detection of leaks by prior art methods fails to reduce the risk of dangerous blood loss to an acceptable level. In general, the risk of leakage-related deaths increases with the decrease in medical staff per

patient driven by the high cost of trained staff.

Currently, with lower staffing levels comes the increased risk of unattended leaks. Thus, there has been, and continues to be, a need in the prior art for a foolproof approach to detection of a return line leak or disconnection.

[0018] In an area unrelated to leak detection, U.S. Pat. No. 6,177,049 B1 suggests the idea of reversing the direction of blood flow for purposes of patency testing. The patent also states that flow reversal may be used to improve patency by clearing obstructed flow.

[0019] US Patent 6,572,576 discusses various embodiments of a blood treatment device where blood flow is reversed to provide leak detection. According to the inventions described, a leak detector effective to ensure detection of leaks in the venous blood line (the line returning blood to the patient) is provided by periodically generating a negative pressure, which may be brief or at a 50% duty cycle, in the blood return line. This draws air into the venous line which can be revealed by an air sensor in the blood treatment machine. During the negative pressure cycle, any air drawn in the venous blood line is detected, the system is shut down and an alarm generated.

US Patent 6,572,576, filed July 7, 2001 entitled "Method and apparatus for leak detection in a fluid line" is hereby incorporated by reference as if fully set forth in its entirety herein.

[0020] Hemofiltration, dialysis, hemodiafiltration, and other extracorporeal blood treatments may employ flow selector valves such as Y-valves, four-way valves, and other such devices for redirecting the flow of blood and other fluids such as replacement fluids. For example, the direction of the flow of blood through certain types of filters may be reversed repeatedly to prevent coagulation of blood in regions where the mean flow slows to very low rates. For example, where blood is circulated through tubular media in the context of a dialysis filter, it has been proposed that blood may coagulate on the surface of the inlet header leading to the progressive coagulation of blood. U.S. Pat. No. 5,605,630, proposes occasionally reversing the flow of blood through the filter. A four-way valve is proposed for changing over the flow direction.

[0021] In other references, the idea of reversing the flow of blood through a tubular media filter is discussed in connection with other issues. For example, in U.S. Pat. No. 5,894,011, the known technique of switching access

lines in the patient to improve the flow through an occluded fistula is automated by the addition of a four-way valve on the patient-side blood circuit. In single-access systems in general, for example as described in U.S. Pat. No. 5,120,303, flow is conventionally reversed through the filter during each draw/return cycle. In the '303 reference, the specification observes that the efficiency of filtration is increased due to the double-passing of the same blood through the filter; that is, each volume of drawn blood is filtered twice. Yet another reference, U.S. Pat. No. 6,189,388 B1, discusses reversing the flow direction of blood through the patient access occasionally in order to quantify an undesirable short-circuit effect that attends their long term use. Still another U.S. Pat. No. 6,177,049 B1 suggests reversing flow through the draw access before treatment while an observer is present to test the accesses for patency or to clear blockage in the accesses.

[0022] Referring to FIGS. 1A through 1E, a number of alternative designs for four-way valves have been developed for blood circuits. Referring to FIG. 1A, U.S. Pat. No. 5,894,011, discloses a valve that swaps the connections between pairs of lines 905 and 906 via a pair of rotatably

connected disks 901 and 902, each of which supports one of the pairs of lines 905 and 906. A seal must be maintained between the disks 901 and 902 and between the respective lines. The device is intended to be operated manually.

[0023] Referring to FIG. 1B, another four-way valve, disclosed in U.S. Pat. No. 5,605,630, which has been proposed for use in blood lines, has a rotating wheel 910 with channels 911 and 912 defined between the wheel 910 and the inside of a housing 913. When the wheel is rotated, the channels 911 and 912 shift to join a different pair of lines. This device also has seals.

[0024] Referring to FIG. 1C, another arrangement is proposed in U.S. Pat. No. 6,177,049. This device has a rotating component 915 with channels 921 and 922 defined within it. As the rotating component 915 is rotated, the channels defined between pairs of lines 917 and 919 change from parallel lines joining one set of corresponding lines to U-shaped channels joining a different set.

[0025] Referring to FIGS. 1D1 and 1D2, a design, disclosed in U.S. Pat. No. 4,885,087, is very similar to that of FIG. 1B. This design has a rotator 925 that connects different pairs of lines depending on the position

thereby defining two different sets of possible flow channels 926 and 929 or 927 and 931.

[0026] In all of the above designs, the valves are not hermetically sealed. Any seal can be compromised, particularly by microorganisms. Thus, each of the foregoing designs suffers from that drawback. Also, many are expensive and do not lend themselves to automation.

[0027] Referring to FIG. 1E, another type of four-way valve is formed by interconnecting two tubes 937 and 938 with crossover lines 935 and 936. This design is disclosed in U.S. Pat. No. 6,189,388 (Hereafter, "U.S. Pat. No. '388"). Tube pinching actuators 941-944 are used to force fluid through different channels, depending on which actuators are closed. This device provides a hermetic seal and can be fairly inexpensive, but in a given configuration, significant no-flow areas are defined. These dead spaces can lead to the coagulation of blood, which is undesirable. Also, the interconnection of tubes in this does not lend itself to automated manufacturing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Figs. 1A, 1B, 1C, 1D1, 1D2, and 1E illustrate various flow reversing devices according to the prior art.

[0029] Fig. 2A illustrates a flow circuit including a blood treatment machine and a sensor module.

[0030] Fig. 2B illustrates a flow reversing portion of the blood treatment machine of Fig. 2A.

[0031] Fig. 3A illustrates a flow circuit including a blood treatment machine, a flow reversing module.

[0032] Fig. 3B illustrates features of the flow reversing module of Fig. 3A.

[0033] Fig. 3C illustrates a flow circuit including a blood treatment machine, a flow reversing module, and a sensor module.

[0034] Fig. 3D illustrates details of a sensor module.

[0035] Fig. 3E illustrates a detail of a flow circuit with a flow reversing module and separate sensor modules.

[0036] Fig. 4A illustrates a portion of a fluid circuit that is interoperable with an actuator to form a flow reversing device.

[0037] Fig. 4B illustrates an actuator interoperable with the fluid circuit portion illustrated in Fig. 4A.

[0038] Figs 5A and 5B illustrate two operating modes of a flow reverser defined by the combination of the devices of Figs. 4A and 4B.

[0039] Fig. 6 illustrate a flow reversing actuator according to an alternative embodiment to that of Figs. 4A, 4B, 5A, and 5B.

[0040] Fig. 7 illustrates a flow reversing device according to an alternative embodiment to that of Figs. 4A, 4B, 5A, and 5B.

[0041] Fig. 8A illustrates a sensor module embedded in a soft outer casing.

[0042] Fig. 8B illustrates a compact longitudinal reversing module.

[0043] Figs. 9A-9C illustrate a first embodiment of a fluid circuit portion and an actuator for providing a compact longitudinal flow reverser.

[0044] Figs. 10A and 10B illustrate a second embodiment of an actuator for providing a compact longitudinal flow reverser.

DESCRIPTION OF THE EMBODIMENTS

[0045] Referring now to Fig. 2A, a patient 130 is connected by an access 139 to a blood processing machine 315. The latter draws blood through an arterial blood line 305 and returns treated blood to the patient 130 through a venous blood line 307. The blood processing machine 315 may be any treatment device such as a hemodialysis machine, a hemofiltration machine, an infusion pump (in which case no arterial line 305 would be present), etc.

[0046] Access 139 may consist of various devices such as a fistula (not shown) and catheter (not shown) combination or other type of access which may be disconnected by various means. For example, a needle (not shown) may be withdrawn from a fistula (not shown) or a catheter from a blood vessel (not shown) disconnected from the arterial 307 and venous 305 lines by means of a luer connector (not shown). The above are conventional features of which a variety of alternatives are known.

[0047] One or more bubble or air sensors (not shown) are provided in a sensor module 311. The sensor module 311 is connected to the blood processing machine 315 by means of a signal line 302. The signal line 302 applies a signal

indicating the presence of air or bubbles in one or both of the arterial 307 and venous 305 lines. The sensor module 311 may be lightweight snap-on module that clamps onto the arterial 307 and venous 305 lines. As is common in blood treatment systems, the arterial 307 and venous 305 lines are clear plastic such as PVC. The sensor module 311 may also include a sensor to indicate the presence of blood in the arterial 307 and venous 305 lines as well. The latter signal may be used for indicating and controlling a transition from a priming mode where the arterial 307 and venous 305 lines carry sterile fluid to a treatment mode where the arterial 307 and venous 305 lines carry blood.

[0048] Referring now also to Fig. 2, the blood processing machine 315 may include, along with various other hardware elements, a flow reversing valve 327. The flow reversing valve 327 may be controlled by an electronic controller 323 to cause the flow through the arterial 307 and venous 305 lines to reverse. In a normal treatment mode, the flow may be as indicated by arrows 301A and during a test mode, in which flow is reversed, blood flow may be as indicated by arrows 301B. During both treatment and test modes, the flow of blood on the other side of the reversing valve 327 may remain as indicated by arrows 301C.

[0049] During treatment, the reversing valve 327 is periodically actuated to place the reversing valve 327 in the test mode. This generates a negative gage pressure in the venous line 305. If any leaks are present in the venous line 305 between the patient 130 and the sensor module 311, air will infiltrate the venous line 305 and be detected by the air or bubble detector within the sensor module 311. The resulting signal may be applied to the controller 323. The controller 323 may be configured to respond by controlling one or more line clamps as indicated at 317 to stop the flow of blood and trigger an over-pressure alarm in the blood processing machine 315 if the latter is provided with one. The controller may also activate an alarm (not shown). The controller may alternatively maintain the test mode to continue flow in the reversed direction in which case, if the blood processing machine 315 is provided with an internal air or bubble detector (not shown), the latter will be triggered by the infiltrating air as if the air had been drawn by the arterial line in the first instance.

[0050] Although a flow reversing valve 327 is illustrated in Fig. 2B, alternative mechanisms for generating a negative pressure in the venous line 305 as

discussed in references incorporated by reference in the instant specification. Also, while one line clamp 317 is illustrated, more clamps may be employed to prevent the loss of blood. For example, a clamp may be provided in the venous line 305. Note that the use of a sensor module 311 as illustrated allows the sensors to be located close to the patient. Consequently, the system can respond quickly to a disconnection of the arterial 307 or venous 305 lines. One of the common types of leaks the system may protect against is an improperly installed or defective connection between the venous 305 or arterial 307 line and the catheter (not shown).

[0051] Referring now to Figs. 3A and 3B, a combined flow reversing and sensor module 333 houses a flow reversing valve 351 and at least one sensor 352A. Flow through venous 325 and arterial 327 lines may be reversed in portions 337 and 335, respectively, by reversing the flow reversing valve 351. The sensor 352A may include a bubble or air sensor, a blood sensor, or both. The sensor module 333 or any of the other sensor modules described herein may include other types of sensors such as pressure sensors to detect a loss of patency at any point in the system. In the foregoing embodiments, the blood or air (or

bubble) sensors may include non-wetted conductivity sensors or non-wetted conductivity cells such as optical (opacity or hue) sensors or any sensor suitable for detecting the presence of air or blood in a clear liquid. The sensor module may also be used to detect other properties or conditions near the patient access such as a sudden acceleration (by means of an accelerometer) due to detachment and subsequent falling out of a catheter, for example. An additional sensor 352B, which may be identical to sensor 352A, may be employed to provide an indication of air infiltration during normal operation in a forward blood-flow direction.

[0052] A controller 349 may be provided to periodically control the flow reversing valve 351. The controller may activate a line clamp 326. The controller may respond to the detection of air in the same manner as described with respect to the foregoing embodiments or as described in the references incorporated in the instant specification, for example, by clamping the line. A signal line 329 may be provided to transmit detector and/or controller signals to the blood processing machine 320. Blood processing machine 320 may be similar to that described with reference to the previous embodiments (e.g.

315 in Figs. 2A and 2B), but preferably it does not include the reversing valve 351. As in previous embodiment, in a normal treatment mode, the flow may be as indicated by arrows 301A and during a test mode, in which flow is reversed, blood flow may be as indicated by arrows 301B. During both treatment and test modes, the flow of blood on the other side of the reversing valve 351 may remain as indicated by arrows 301C.

[0053] Referring now to Fig. 3C, the blood processing machine 320, the same as the one described with reference to Fig. 3A, is linked by venous 373 and arterial 375 blood lines to a flow reversing module 370. A sensor module 377 is located close to the access 139 and is coupled to the reversing module 370 by a signal line 378. Venous 374A and arterial 376A lines link the reversing module 370 to the access 139 for supply and return flows of blood (with reference to the patient 130), respectively. Portions of venous 374B and arterial 376B lines pass through the sensor module 377 to the access 139. The configuration of Fig. 3C, as in the configuration of Figs. 2A and 2B allows the sensor module 377 to be located close to the patient 130 and for the reversing module 370 to be retrofitted to a blood treatment machine 315 that is otherwise not

configured for leak detection in the fashion described.

Thus Figs. 3A-3C are attractive for retrofit applications where leak detection capability is to be added to a blood processing machine 315 otherwise not configured for it.

[0054] Internally, the flow reversing module 370 may be identical to that shown in Fig. 3B. The sensor(s) 352 may or may not be present to protect against leaks in the portions of the venous and arterial lines 374A and 376A as well as the portions 374B and 376B which are protected by sensors in the sensor module 377. Note also that signal line 378 or any of the foregoing signal lines may represent wireless links, acoustical signal links, or any suitable means of communication. Also, the various devices may be powered by battery or by electrical lines.

[0055] Referring to Fig. 3D, a sensor module 380 has features which may be employed in sensor modules 311 (Fig. 2A) and 377 (Fig. 3C) described above. Air detectors 401 and 407 detect air passing through lines 374 and 376, respectively. Blood sensors 403 and 405 may be included in the sensor module 380 to detect blood in lines 374 and 376, respectively. Note that in another embodiment, the sensor module 380 only contains sensors for a single line 374, which is preferably the venous line of the foregoing

embodiments. In yet another embodiment, the entire sensor module 380 is connected around a single line 374, which is preferably the venous line of the foregoing embodiments. In the latter case, only the upper part 380A is present and the other half 380B on the other side of line 380C is not present. Note that alternatively, both lines may be provided with separate sensor modules 390A and 390B in an alternative embodiment as illustrated at Fig. 3E. Note also that two adjacent flow lines may be protected by a single air detector or blood detector or both.

[0056] A key 409 of any desired shape may be placed on one of the lines 374 or 376 which fits into a slot 411 and engages a detector 410 to indicate its proper insertion into the slot 411. The key 409 and slot 411 ensure that if only one line 374 is protected by air sensor 401, that it is the venous line. Otherwise the protection system wherein flow is reversed to indicate a leak would serve no purpose. The detector 410 may send a signal along the signal line 378 to indicate proper insertion. A failure of proper insertion while attempting to operate the system may cause the system to generate an alarm. A door 406 may be closed over the lines 374 and/or 376 to lock them in place.

Electronic equivalents of key 409 and sensor 410 may also be provided.

[0057] Referring to Figs. 4A and 4B, in an embodiment of a compact and reliable flow reversing device, a portion of a fluid circuit 224 includes a toroidal portion 226 with ports A, B, C, and D linked by segments 221A, 221B, 221C, and 221D as illustrated. Fluid lines 203, 205, 207, and 209 connect with respective ones of ports A, B, C, and D. The toroidal portion and portions of fluid lines 203, 205, 207, and 209 fit into channels 211, 215, 211, and 217 of an actuator 221. The actuator 221 contains a rotatable clamp 222 with two edges 238 and 237 which selectively pinch segments 221A, 221B, 221C, and 221D between the edges 238 and 237 and edges 231, 229, 235, and 233 of the actuator 221, respectively as illustrated in Figs. 5A and 5B.

[0058] Referring now to Fig. 5A, the toroidal portion 226 may be of a compliant and stretchable material that permits it to be forced into position in the actuator 221 and partly deformed as illustrated. The clamp 22 may be in the neutral position illustrated in Fig. 4B when this is done. During operation, when clamp 222 is in a first position indicated in Fig. 5A, segments 221B and 221D are clamped closed allowing a flow between line 209 to 207 and

from line 205 to line 203 as indicated by arrows 225A and 227A. As will be observed, segment 221B is pinched between edges 238 and 231 while segment 221D is pinched between edges 237 and 235. The path of lines 209 to 207 may correspond to flow through the venous lines of the previous embodiments. For example, with reference to Fig. 3A, line 209 may correspond to line 325 and line 207 to line 337. Similarly, the path of lines 205 to 203 may correspond to flow through the arterial lines of the previous embodiments. For example, with reference to Fig. 3A, line 205 may correspond to line 335 and line 203 to line 329. In the configuration of Fig. 5A, the flow may then provide for normal blood flow for treatment by allowing line 207 to flow blood to a patient and return through line 205 to pass through the flow reverser back to a blood treatment machine.

[0059] Referring now to Fig. 5B, when clamp 222 is in a first position indicated in Fig. 5B, segments 221A and 221C are clamped closed allowing a flow between line 209 to 205 and from line 207 to line 203 as indicated by arrows 225B and 227B. In the configuration of Fig. 5B, the flow may then provide for reverse blood flow for testing by allowing line 205 to flow blood to a patient and return

through line 207 to pass through the flow reverser back to a blood treatment machine. This results in a negative pressure in line 207 whereupon if any disconnections or leaks occur, air will be drawn into line 207 which may be revealed by a sensor, as discussed with reference to the figures above.

[0060] Referring now to Figs. 6 and 7, in alternative embodiments of the flow reverser of Figs. 5A and 5B a clamp 427 may be passively mounted on a door 424 and engaged with a drive bolt 443 in a chassis portion 421 of a flow reverser. The drive bolt 443 may fit as a key in a recess 441 thereby driving the clamp. The closure of the door 424 may be indicated by a detector which may send a signal to a controller permitting the drive bolt 443 to be operated according to the configuration of a controller (e.g., 349 of Fig. 3B). Instead of a single rotating clamp located at a center of a flow reverser, respective clamps 451A, 451B, 451C, and 451D may pinch respective portions of the flow circuit toroidal portion 226 by means of a shaped boss 449 that fits into the center of the toroidal portion 226. The clamps 451A, 451B, 451C, and 451D may be operated by respective drives such as solenoids (not shown) or coupled to be operable with one or two drives as desired.

[0061] Referring to Fig. 8A, to permit a flow reverser or sensor module to be placed close to the patient but allow for patient comfort, the flow reverser or sensor module 379 may be fitted into a soft shell 501. The latter may have a shape such as a teddy bear or other stuffed animal or ornament.

[0062] Referring to Fig. 8B, preferably the flow reverser is of a compact longitudinal shape with the lines 667 and 669 leading to the blood treatment machine stemming from one end and the lines and the lines 663 and 665 leading to the patient access stemming from the opposite end. This may allow the flow reverser 661 to lie close to the patient access and self-orient in a comfortable and unobtrusive manner.

[0063] Referring to Figs. 9A, 9B, and 9C, two Y-junctions 503 and 505 may be connected to a patient access and two other Y-junctions may be connected to a blood treatment machine or remainder thereof. Two double-edged clamps 519 and 521 are driven by a double-axis motor drive 527 that rotates one clamp 519 in one direction and the other clamp 521 in the opposite direction, for example by providing that one clamp is connected to the stator and one connected to the rotor of the motor. It is contemplated

that a reduction drive would be employed to increase the torque of the primary motor within the drive 527 and allow a small motor (not shown separately) to be used. A support stalk 502 holds the drive 527 so that it is free to rotate with respect to it, thereby providing a mounting to a housing such as illustrated in Fig. 8B. Each segment 511, 513, 515, and 517 may be selectively pinched by as illustrated in Figs. 9B and 9C to provide for forward and reverse flow between one pair of junctions 505/503 or 509/507. The clamps may be tapered to provide a high clamping pressure as indicated at 535, 533, 523, and 525 and similarly on portions opposite the edges indicated at 535, 533, 523, and 525.

[0064] Referring to Figs. 10A and 10B, another flow reversing device using a fluid circuit portion as illustrated in Fig. 9A producing four parallel segments 511, 513, 515, and 517 is driven by a linear drive (not shown) that moves a stalk 607 along an axis thereof. Cams 617 and 619 are forced into an opposing pair of tube segments 605 and 611 when a large diameter portion 627 of the stalk 607 is forced between the cams 617 and 619 by pushing the stalk 607 in a first direction (to the left). Cams 617 and 619 are forced into an opposing pair of tube

segments 633 and 635 when a large diameter portion 627 of the stalk 607 is forced between the cams 610 and 621 by pushing the stalk 607 in a second opposite direction (to the right). The segments may be held in position by a frame of two portions 613 and 615 which close around a cam frame 607. Edges 609 and 611 are provided to amplify the pinching stress and cooperative with cams 617 and 619 to clamp the tubes segments 603 and 609.

[0065] Referring to Fig. 11, an operating regimen begins with a priming of a fluid circuit at step S10. The priming mode is initiated by a priming command being received by the flow reverser controller at step S10. The flow reverser controller places the flow reverser in forward mode so that fluid is pumped in a single direction. The controller may be configured to operate for flow in a single direction continuously as long as no blood is detected by blood sensors in the sensor module or in the blood treatment machine. The pump may be operated at step S20 for a desired period of time to prime the blood circuit and other portions of the fluid circuit used for treatment. At some point during the priming mode, the operator may halt the pump, clamp various lines, and make certain

connections in preparation for treatment and restart the pump. All these steps are assumed to fall within step S20.

[0066] When the flow reverser controller detects blood in step S25, control flow exits to step S30 and flow continues in the same direction for a specified period of time which may be proportional to the mass flow rate of blood. The blood will ordinarily be detected because of the connection changes of the operator who has determined that the system is adequately primed and has remade connections as required. This may also be an automated process as well depending on the blood processing system and the level of automation. Referring now also to Fig. 12, once the initial forward operation period has elapsed at step S30, the flow reverser control may go into an operating mode where it periodically reverses flow 830 for a fixed interval test cycle 820 to generate a temporary negative pressure and reverse flow to test the venous line and then returns to forward operation 835. Generally, the test cycle 820 interval will be shorter than the normal forward treatment 825 interval. In addition to the test cycle, short duration reverse cycles 810 of a higher frequency may be included to clear the dead legs of the flow reversing device. Referring momentarily to Fig. 13,

the shaded regions 815 in the embodiment of Figs. 5A and 5B in the normal flow direction represent areas with no flow. If the blood in these regions is allowed to stagnate for an extended time, clotting may occur. To help prevent this, the flow may be reversed for very short intervals to cause a flow in these otherwise continuously non-flow regions 855. A train of such dead-leg clearing cycles is shown in Fig. 12 at 810.

[0067] Returning to Fig. 11, the cyclical operation of Fig. 12 may continue until a treatment is completed or until air is detected (or some other malfunction causes treatment to be terminated). If air is detected at step S41, a fault procedure is followed in step S56. For retrofit embodiments of the flow reversing leak detection system such as illustrated in Figs. 3A and 3C for example, it is desirable for the flow reversing controller to respond to air detection in a manner that ensures an appropriate response without some sort of control connection or control collaboration between the flow reversing module (e.g. 370, Fig. 3C) and the blood treatment machine 320. Thus, preferably the flow reversing module control's 349 response should ensure appropriate action. Referring now to Fig. 14A, to that end a response

S45A for step S56, when air is detected (S48) at step S41, the blood lines may be clamped at step S60 to induce a high pressure in the blood treatment machine which in most type of blood treatment machines would trigger a shutdown and error indication by the machine. This may be provided by means of a clamp as indicated at 326 or 317 in Figs. 3B and 2B respectively, for example. Referring to Fig. 14B, another response for step S56 is step S45A in which a shutdown by the main processing machine is induced in step S65 to continue operating in reverse mode until the air that was detected by the flow reversing module triggers an air detection by the blood processing machine.

[0068] When a blood treatment has reached a point where an adequate quantity of blood has been treated, an operator may flush the patient's blood back into the patient by changing a configuration of the blood treatment machine. At some point during such a change in operation, clear fluid may be detected by the sensor module or sensors embedded in the blood treatment machine depending on the embodiment. Detection of clear fluid in step S42 may cause the flow reverser to halt the forward/reverse cycling and operate continuously in forward mode to allow the flush to be completed. Once completed in step S50, the treatment

may be terminated by the operator. A control on the flow reverser may be provided for it. Alternatively, a pressure switch or interlock with the blood treatment machine may indicate a no-flow condition in which case the flow reverser may be placed in a neutral position for disengagement of the tubing set.

[0069] Note that by placing the air sensor close to a patient as described in the foregoing embodiments, the reverse cycle may be kept to a minimum duration. Preferably this duration is established to provide the minimum volume displacement needed to cause any air bubbles leaking into the blood line to reach the air sensor in the sensor module. This may be established in the flow reverser by means of an input from a user or by calculating from a measured flow rate. Thus, a flow rate sensor may be included in the flow reversing module and the controller configured to calculate the amount of time, based on flow rate, to ensure the minimum volume is displaced.

Abstract

A blood processing system includes a flow reversing device with at least an air sensor in the venous line located near the patient. During treatment, blood flow is reversed to cause air to infiltrate the blood lines if any disconnections or breaks in the blood line are present.

One means for placing the sensor close to the patient is to provide the flow switching device and sensors in a small lightweight module that can be located close the treatment machine. Another is to provide a module with just the sensors near the access.

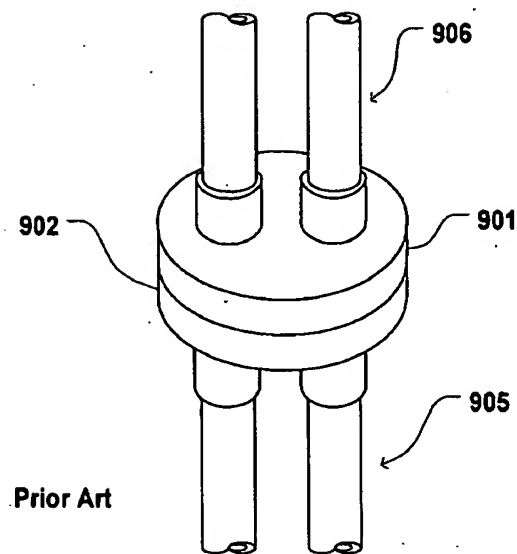


Fig. 1A

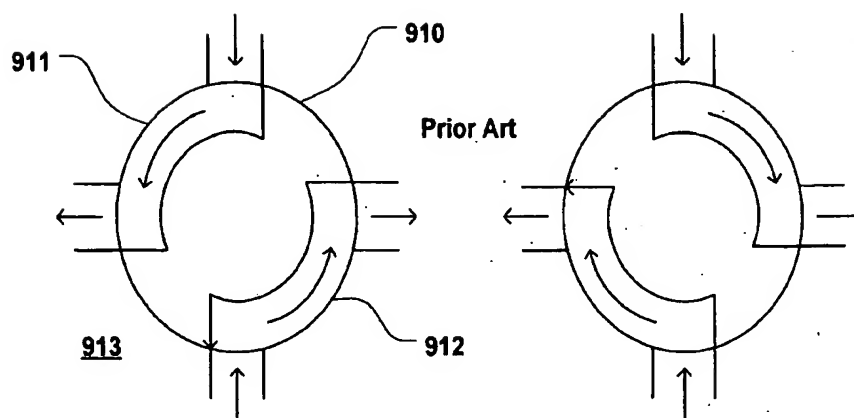


Fig. 1B

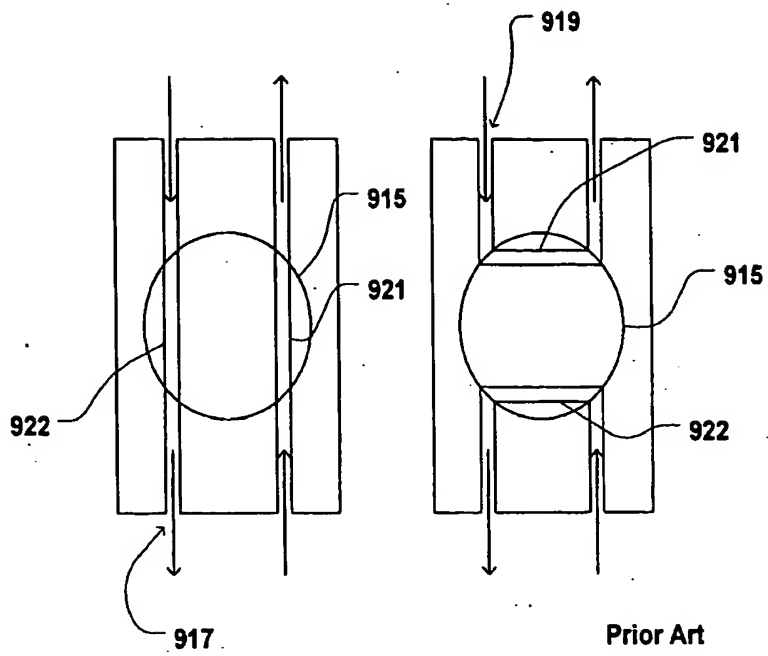


Fig. 1C

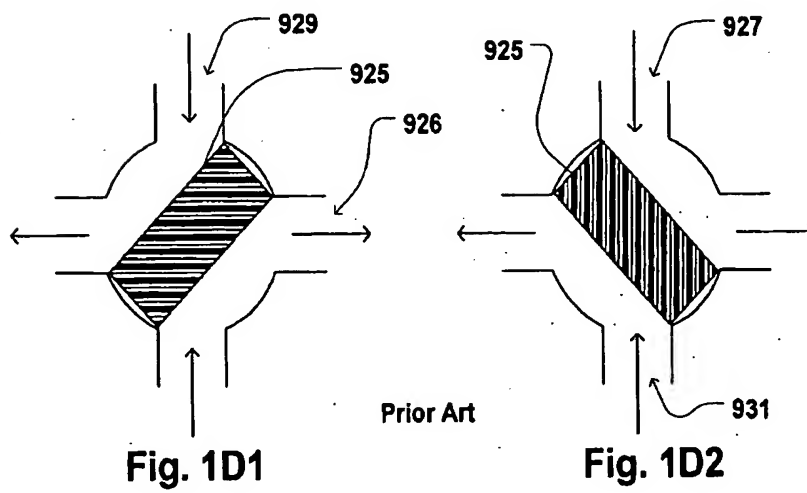
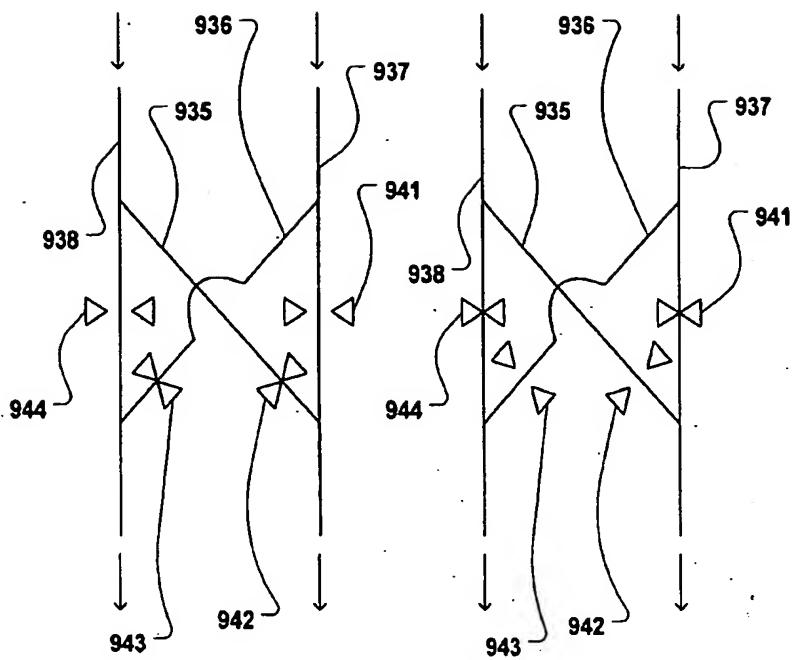


Fig. 1D1

Fig. 1D2



Prior Art

Fig. 1E

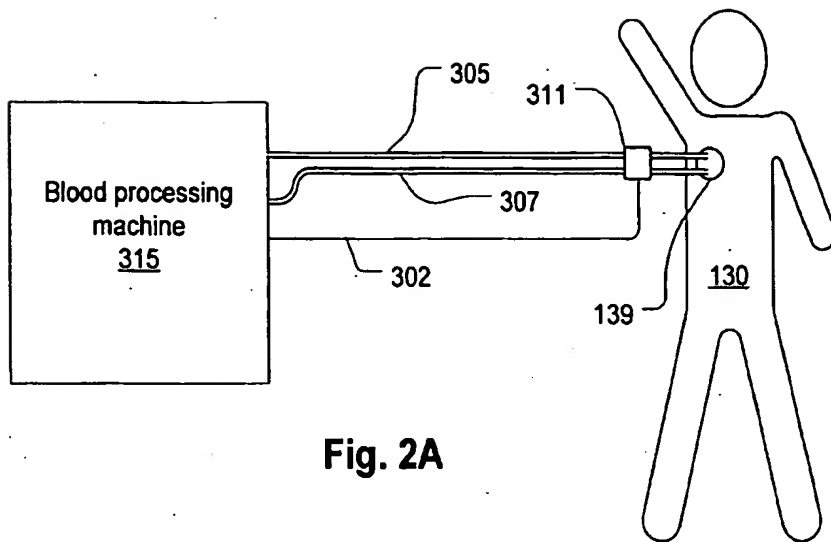


Fig. 2A

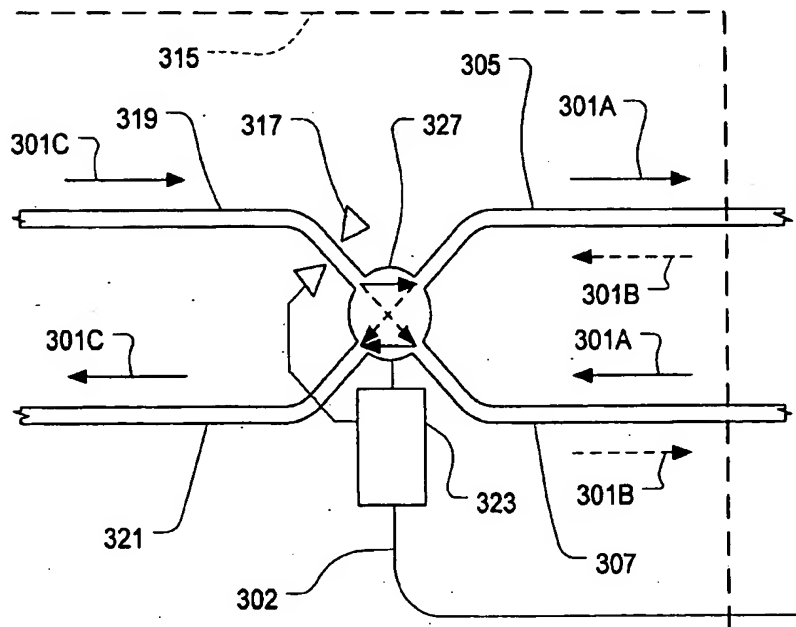
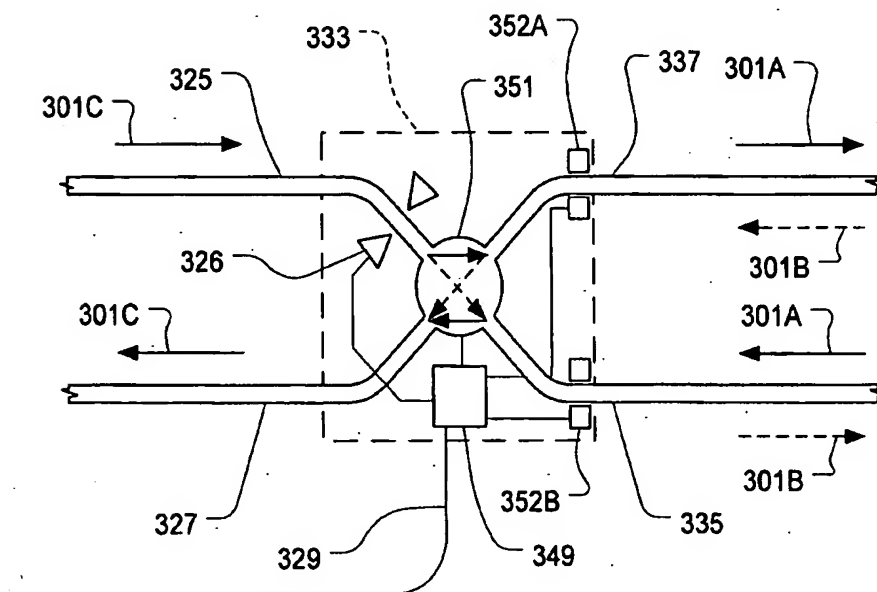
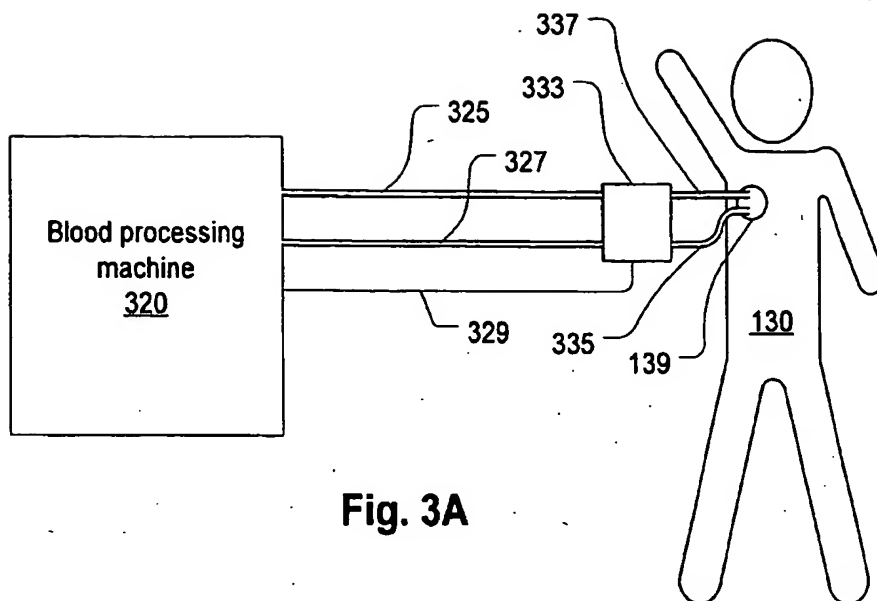
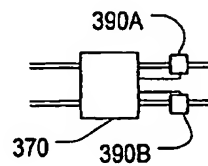
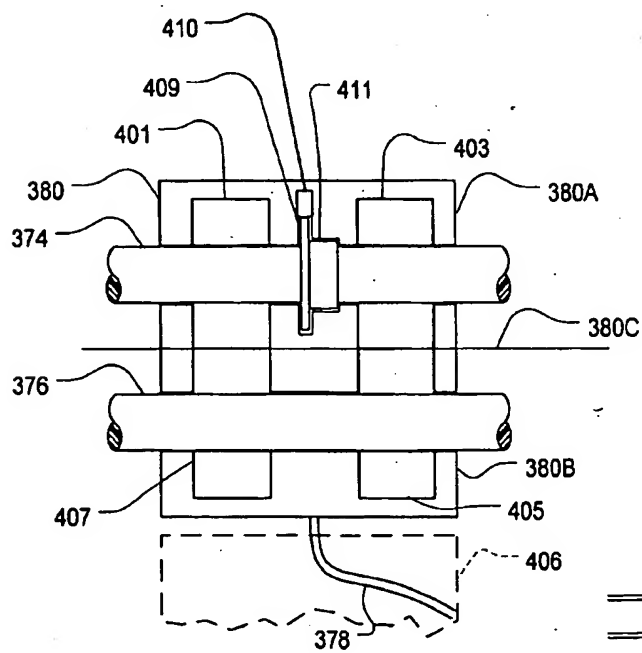
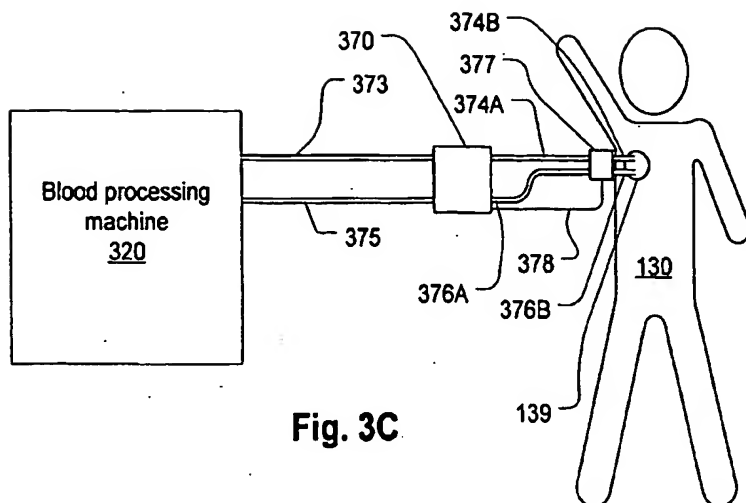


Fig. 2B





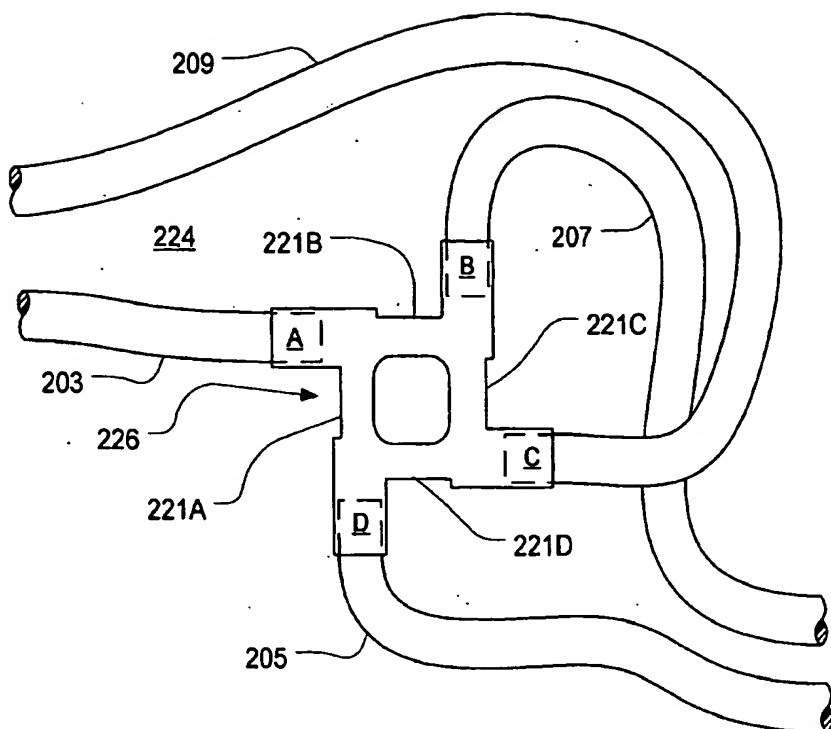


Fig. 4A

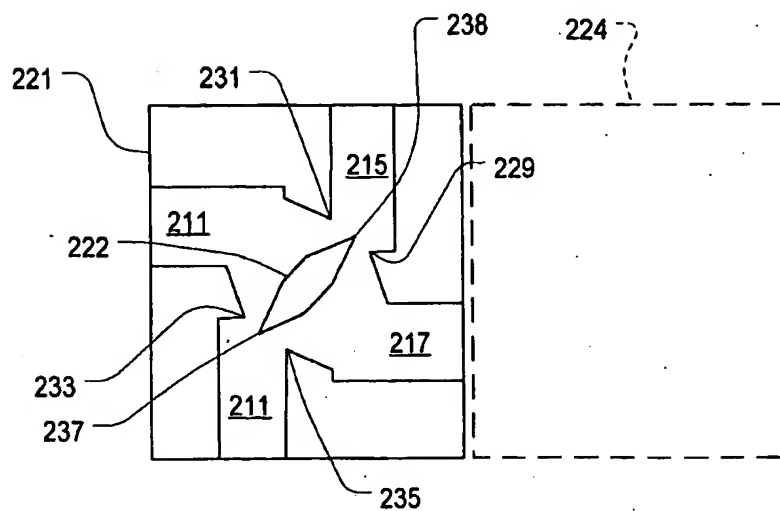
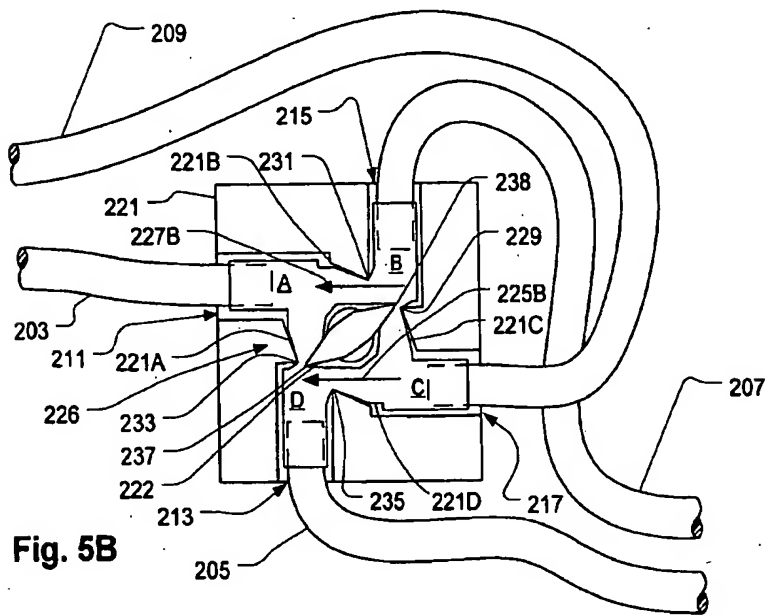
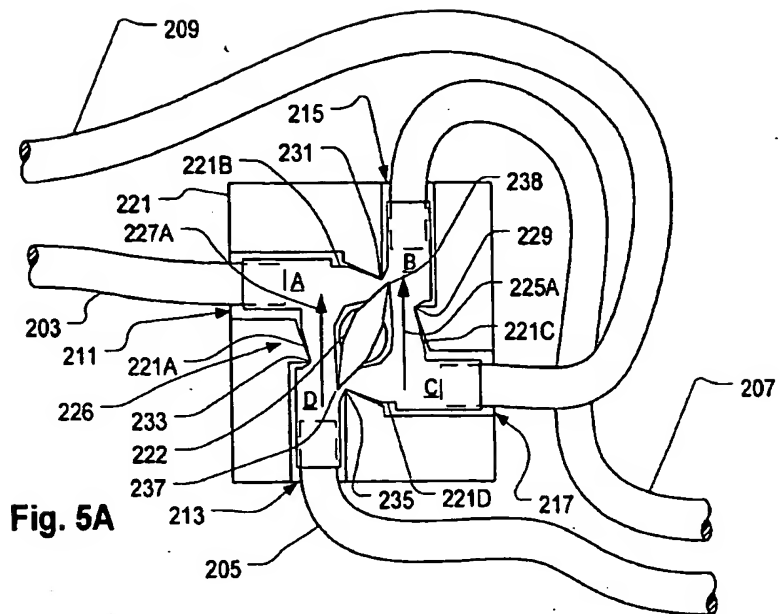


Fig. 4B



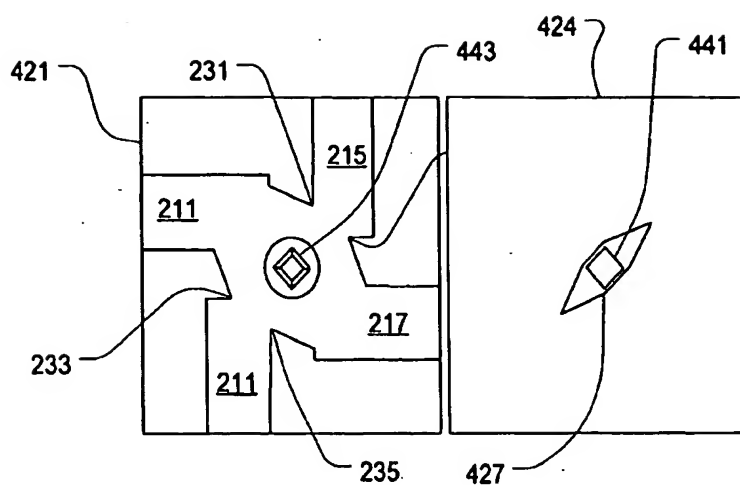


Fig. 6

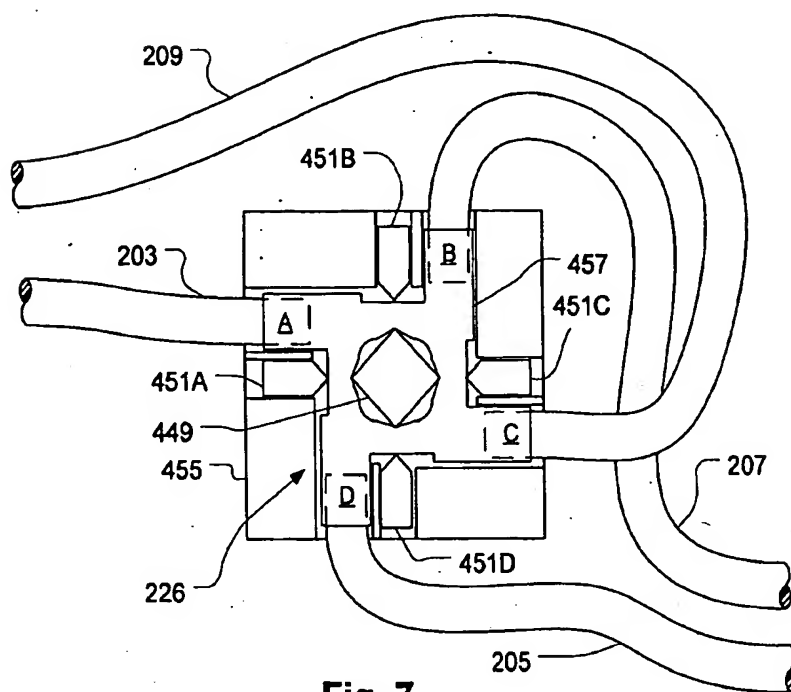


Fig. 7

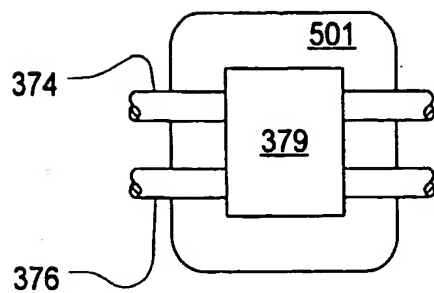


Fig. 8A

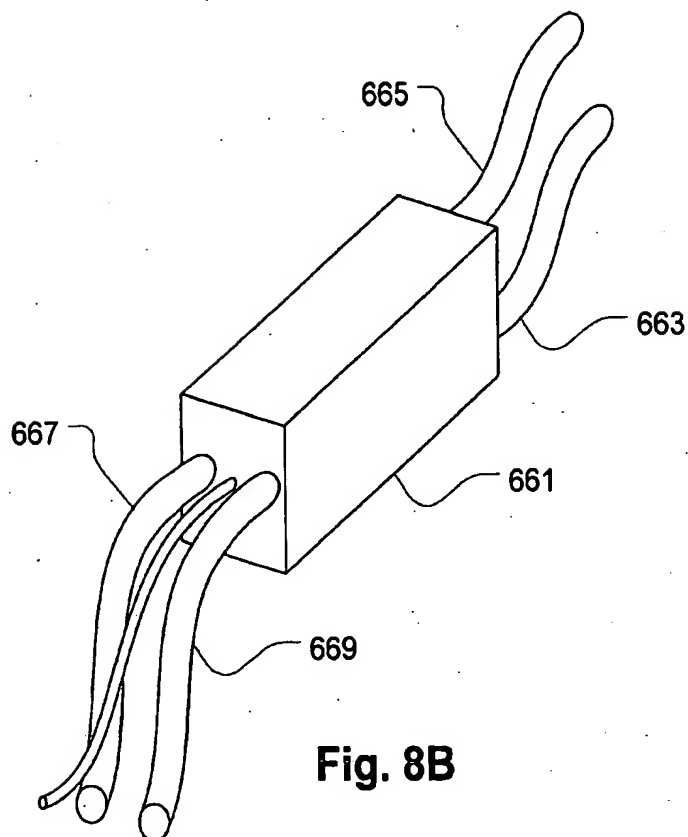


Fig. 8B

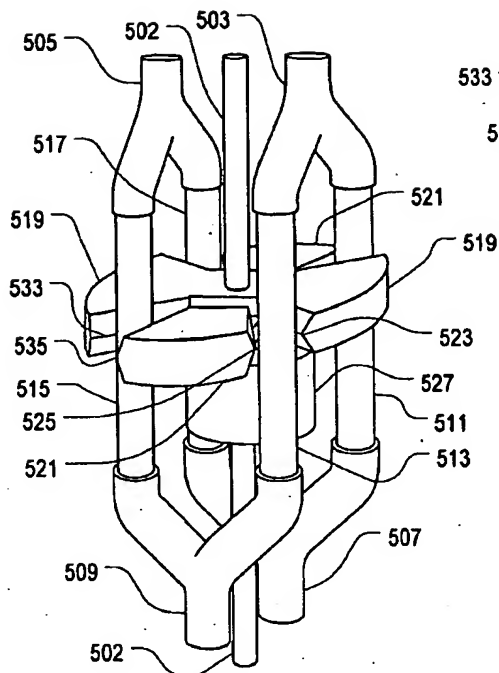


Fig. 9A

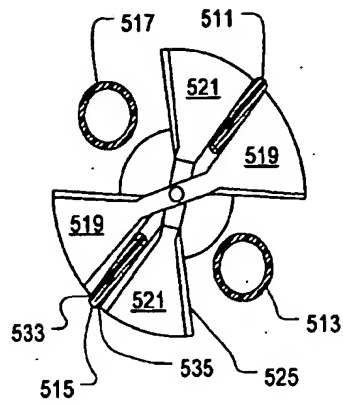


Fig. 9B

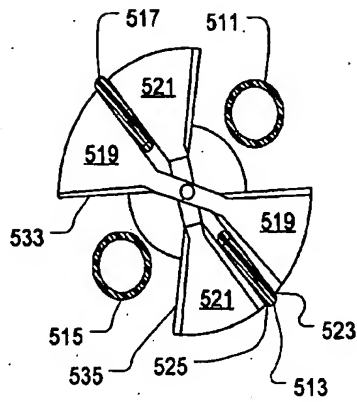


Fig. 9C

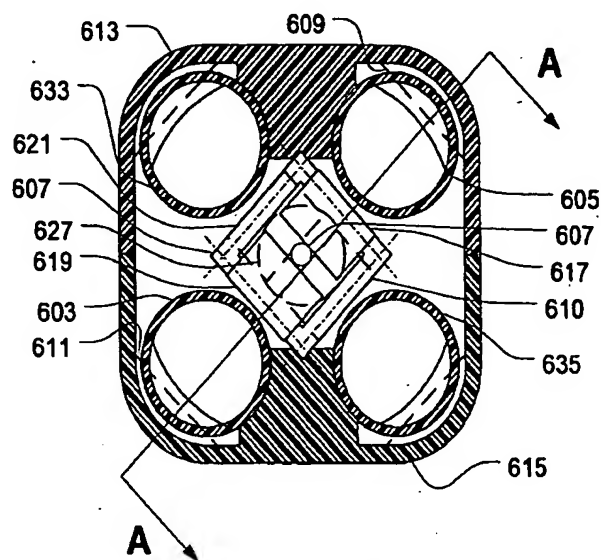


Fig. 10A

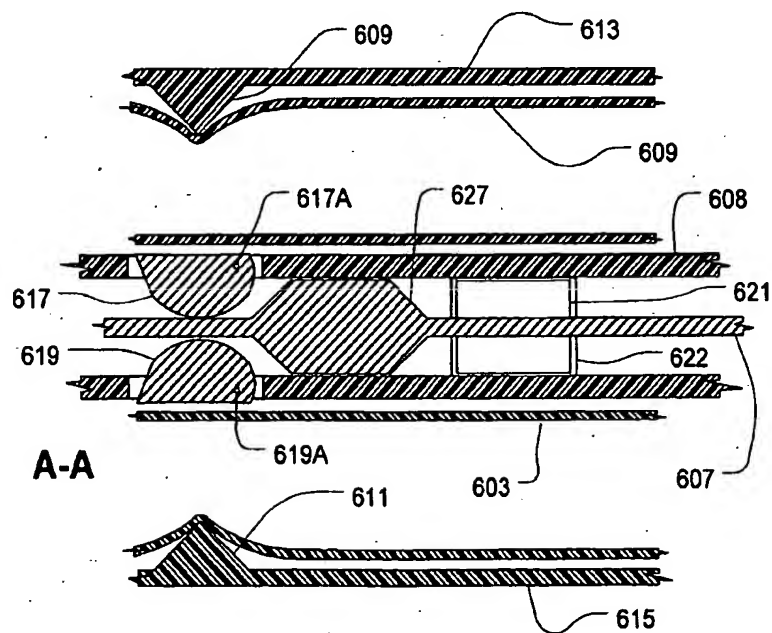


Fig. 10B

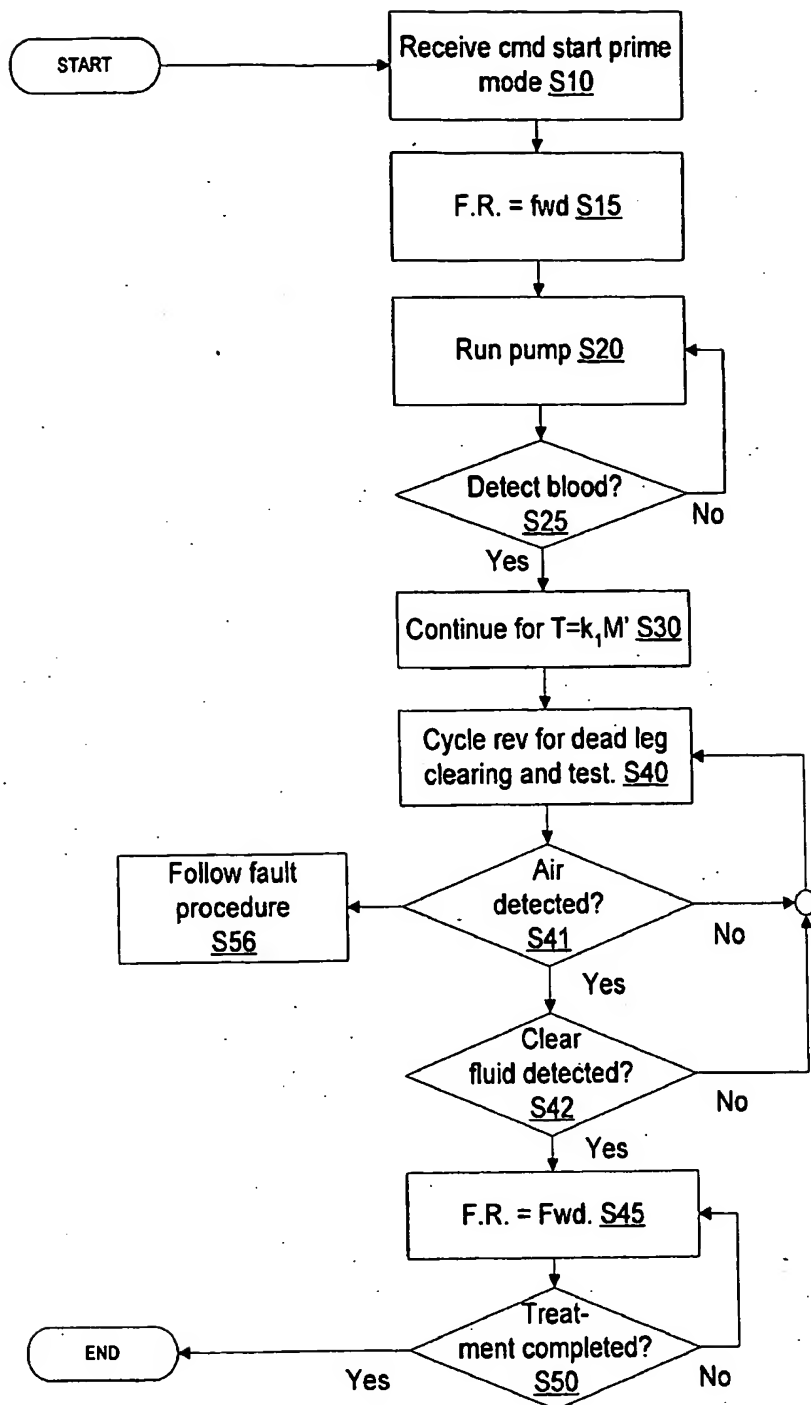
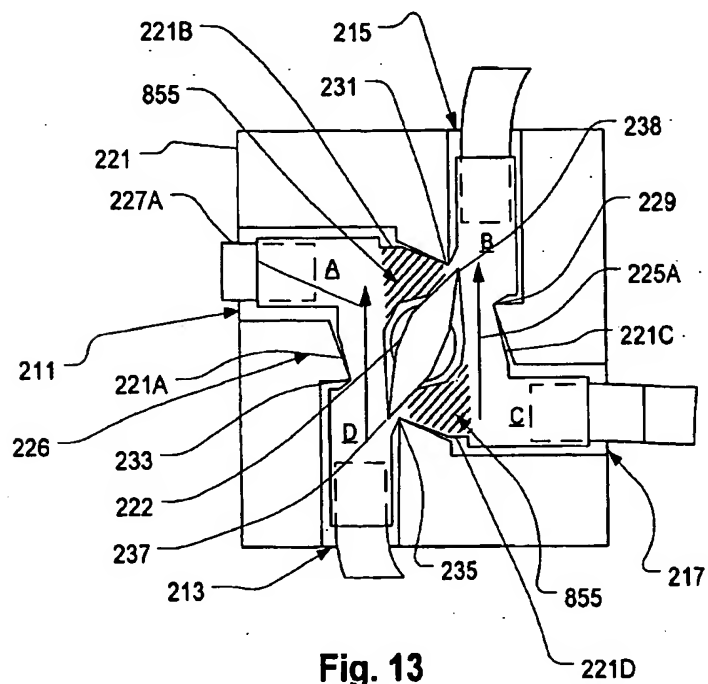
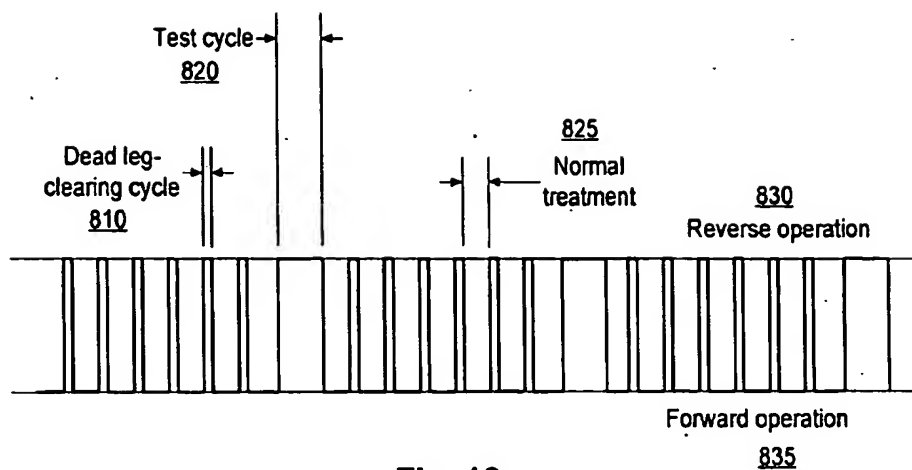
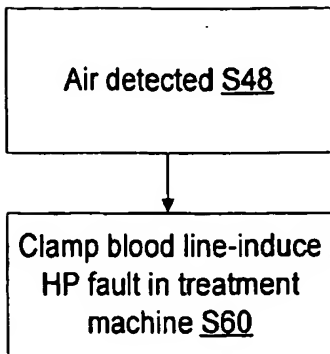


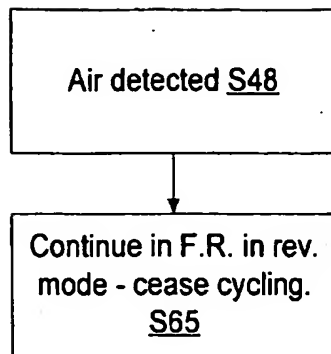
Fig. 11





S45A

Fig. 14A



S45B

Fig. 14B